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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/691,051	10/19/2000	Ronald P. Lesser	P 268412 DM-3580	5363
909	7590	06/16/2004	EXAMINER	
PILLSBURY WINTHROP, LLP			OROPEZA, FRANCES P	
P.O. BOX 10500			ART UNIT	
MCLEAN, VA 22102			PAPER NUMBER	
			3762	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/691,051

**Applicant(s)**

LESSER ET AL.

**Examiner**

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 3/24/04 and 2/9/04 (RCE and Remarks).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 35-62 is/are pending in the application.
- 4a) Of the above claim(s) 47, 48, 50-60 and 62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35-46, 49 and 61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Request for Continued Examination***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The Applicant's submission filed on 3/24/04 has been entered.

### ***Election/Restrictions***

2. Newly submitted claim 62 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Original independent claim 35 does not contain the limitation of "performing a wavelet transform on data obtained from said monitoring to generate wavelet-transformed data".

Since the Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 62 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Claim Rejections - 35 USC § 103***

3. Claims 35-40, 43, 45, 46, 49 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorfmeister et al. (US 5995868) in view of Mizuno-Matsumoto et al. (IEEE article).

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Dorfmeister et al. disclose a system that monitors electrical signals representative of a subject's brain activity and analyzes the signals using a processor (12) to enable treatment (col. 4 @ 64 – col. 5 @ 6; col. 8 @ 37-48). The treatment can be electrical stimulation, cooling or a medicament (col. 6 @ 50-62; col. 9 @ 10-27; col. 32 @ 45-58). Additional sensors provide data on the condition of the patient, including chemical and thermal sensors (col. 9 @ 40-67; col. 13 @ 18-28 and 55-59). Signal processing includes adaptive analysis of waveform characteristics such as wavelet transform analysis (col. 5 @ 6-10; col. 16 @ 32-41).

As discussed in the previous paragraph of this action, Dorfmeister et al. discloses the claimed invention except for the analysis being a cross-correlation analysis (claim 35), the cross-correlation analysis being performed on wavelet-transformed data, the data obtained by performing a wavelet transform on monitored data (claim 61).

Mizuno-Matsumoto et al. teach non-stationary analysis of epileptogenic phenomena using wavelet cross-correlation performed on monitored data that has been wave-transformed for the purpose of identifying and visualizing the localization of epileptogenic foci. Mizuno-Matsumoto et al. performs the cross correlation analysis on "wavelets" in a time series, each wavelet being a 16 Hz, 120 ms epileptiform discharge, found to be ideal for investigating the propagation of a epileptiform discharge wave component. In the wavelet cross correlation analysis, the time series of two data points are analyzed in a common window such that the data is established as wavelets and cross correlated, one time series associated with the signal being evaluated and the other time series being the reference signal (Page 274 - left column - first three paragraphs; Page 275 - Paragraph spanning the left and right columns). It would have been obvious to one having ordinary skill in the art at the time of the invention to have used cross-correlation analysis based on monitored data that has been wave-transformed in the Dorfmeister

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et al. system in order to identify the origin of epileptogenic foci and the propagation path so treatment can be precisely applied (page 271, right column, first paragraph and final paragraph; page 272, right column, first complete paragraph; page 273, the paragraph spanning the left and right column; page 275, left column, first complete paragraph; page 277, right column, second complete paragraph).

The Applicant's arguments filed 2/9/04 have been fully considered, but they are not convincing.

The Applicant asserts the Minzuno-Matsumoto et al. article does not disclose or suggest wavelet cross-correlation analysis and states the Examiner agrees with with position. The Examiner disagrees. The Minzuno-Matsumoto et al. article does disclose wavelet cross-correlation analysis. Minzuno-Matsumoto et al. teach the cross correlation analysis is performed on "wavelets" in a time series, each wavelet being a 16 Hz, 120 ms epileptiform discharge, found to be ideal for investigating the propagation of a epileptiform discharge wave component. In the wavelet cross correlation analysis, the time series of two data points are analyzed in a common window such that the data is established as wavelets and cross correlated, one time series associated with the signal being evaluated and the other time series being the reference signal (Page 274 - left column - first three paragraphs; Page 275 - Paragraph spanning the left and right columns).

The Applicant appears to argue that based on the discussion on page 273 of the Minzuno-Masumoto et al. article, the filtering of a waveform transform to focus on a 16 Hz frequency prevents the filtered waveform from being used as the basis of another analysis method such as a wavelet cross correlation analysis. The Examiner disagrees. The Examiner is

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unable to find in the Minzuno-Matsumoto et al. article on Page 273 discussion of any limitations on the use of the filtered, nominal 16 Hz signal.

As to submitting additional information, the Examiner regrets that the Applicants have apparently misinterpreted her comments. The Examiner does not find the record in this application insufficient. The Applicant's are welcome to submit any additional information they want considered on the record, and the Examiner will be glad to consider it.

4. Claim 41 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorfmeister et al. (US 5995868) in view of Mizuno-Matsumoto et al. (IEEE article) and further in view of Ward et al. (US 5978702). As discussed in paragraph 4 of this action, modified Dorfmeister et al. disclose the claimed invention except for the treatment being electrical pulses (claim 41) and the medicament being a drug such as dopamine agonist (claim 44).

As to the pulses, Ward et al. disclose electrical stimulation techniques for treating epilepsy and teach that it is known to use stimulation pulses to increase medicament efficacy (col. 8 @ 44-46; col. 9 @ 10-12). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified system that analyzes signals representative of a subject's brain activity as taught by modified Dorfmeister et al., with the inclusion of stimulation pulses as taught by Ward et al. to provide a proven means to optimize the impact of the medicament so the seizure is arrested as soon as possible.

As to the drug, Ward et al. disclose drug infusion techniques for treating epilepsy and teach that it is known to use a dopamine agonist to alter the neural environment of the brain (col. 8 @ 37-43 and Table I.). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified system that analyzes signals

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representative of a subject's brain activity as taught by modified Dorfmeister et al., with the inclusion in the medicament delivery system of a dopamine agonist as taught by Ward et al. to provide a specific drug that will alter the neural environment of the brain and alleviate the neural symptoms, specifically seizures.

5. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dorfmeister et al. (US 5995868) in view of Mizuno-Matsumoto et al. (IEEE article) and further in view of King et al. (US 5925070). As discussed in paragraph 4 of this action, modified Dorfmeister et al. discloses the claimed invention except for the charge balance of the current pulse sequence being ordered and maintained by dynamic feedback.

King et al. disclose controlling the locus of excitation of electrically excitable tissue and teach that it is known to provide tissue stimulation based on dynamic feedback to maintain charge balance (col. 10 @ 43-65) to enable optimum tissue stimulation. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified system that analyzes signals representative of a subject's brain activity as taught by modified Dorfmeister et al., with the pulse sequencing using charge balancing as taught by King et al. to provide optimum tissue stimulation by ensuring, with charge balancing, that the tissue is not damaged or destroyed by the imbalance in the charge field during the treatment periods.

#### ***Statutory Basis***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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***Other Prior Art Cited***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5314458 to Najafi et al. teaches charge balancing. US 6594524 to Esteller et al. teaches coherence and cross-correlation (col. 14 @ 60-64; col. 27 @ 55-59; col. 30 @ 10-17).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Friday from 9 a.m. to 5:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza  
Patent Examiner  
Art Unit 3762

FO  
6/13/04

Angela D. Sykes

ANGELA D. SYKES  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700